REMARKS

Claims 1–7, 9, and 10 are pending. In the Office Action, the Examiner issued a restriction requirement under 35 U.S.C. §§ 121 and 372. In the restriction, the Examiner divided the subject matter of the claims into the following groups: Group I (Claims 1–5), Group II (Claims 6, 7, and 9), and Group III (Claim 10). The Examiner asserts, among other things, that the claims of Groups I and II are not so linked as to form a single general inventive concept under PCT Rule 13.1. Based on this, the Examiner contends that Applicant must elect one of these groups for prosecution in this application. However, no mention is made in the remarks about Group III. It is therefore assumed that the restriction is only asserted as between Groups I and II.

In response, Applicant hereby provisionally elects Group I (Claims 1–5) for prosecution in this application, but this election is made with traverse and is solely for the purpose of advancing prosecution of this case. It is believed that the requirement to restrict is improper for the reasons set forth below and the Examiner is respectfully urged to reconsider and withdraw the same.

I. Sufficient Unity Exists Between Applicant's Independent Claims of Groups I and II

The Group I claims are directed to the compound tamsulosin hydrochloride in the amorphous form as a composition of matter. The Group II claims are directed to a process for preparation of the compound tamsulosin hydrochloride in the amorphous form. The Group III claim is directed to a pharmaceutical composition containing, among other things, the compound tamsulosin hydrochloride in the amorphorphous form. Although not germane the matter of the propriety of the asserted restriction, all claims are believed to be novel and nonobvious over the prior art.

The relationships between Groups I and II are quite similar to the relationships given in the very first example (Section 10.21) of Chapter 10 of the International Search and Preliminary Examination Guidelines available to U.S. and WIPO patent examiners. Section 1850 of the M.P.E.P. directs U.S. Patent Examiners to this section for specific examples. Example 1 states as follows:

Claim 1: A method of manufacturing chemical substance X.
Claim 2: Substance X.

> Claim 3: The (method of) use of substance X as an insecticide.
>
> Unity exists between claims 1, 2, and 3. The special technical feature common to all the claims is substance X. However, if substance X is known in the art, unity would be lacking because there would not be a special technical feature common to all the claims.

The Examiner asserts that tamsulosin hydrochloride in the amorphous form is not a patentable feature over the prior art and, as a result, the claims groups of Groups I and II lack unity and must therefore be divided. With all due respect, this is not correct. The Examiner's reasoning is explicitly discouraged by the M.P.E.P. and by Chapter 10 of the International Search and Preliminary Examination Guidelines (as discussed below). Moreover, it absolutely clear from the example above that the combination of the types of independent claims found in Applicant's application are unified because they share in common an assertedly patentable compound.

II. The Amorphous Form of Tamsulosin Hydrochloride Is Novel

The Examiner explicitly concedes that "Miyazawa et al, 2001 does **not** disclose an amorphous form of tamsulosin hydrochloride (emphasis added)." The '300 patent also does **not** disclose an amorphous form of tamsulosin hydrochloride. The Examiner cites the '300 patent at column 7 as listing tamsulosin hydrochloride as a "preferred" drug as if to suggest tamsulosin hydrochloride were specifically discussed and shown to exist in an amorphous form. The Examiner also cites the '300 patent at column 12 in an apparent effort to show any/all drugs mentioned in the '300 patent disclosure are or can be produced in "a crystalline state, an amorphous state, or mixtures thereof depending on how droplets are dried and the excipients present." A closer look at the '300 patent reveals a different story.

First, the Examiner fails to acknowledge that the so-called "preferred" drug tamsulosin hydrochloride is mentioned among a laundry list of drugs that starts on column 4 at line 26 and ends at column 8 on line 9. The list includes about 800 to about 1000 drugs by name. Second, the Examiner's reliance on the language at column 12 proves too much. When considered in proper context, the '300 patent merely states the method described therein may produce a drug in a crystalline state, an amorphous state, **or** mixtures thereof, depending on certain factors. This plainly cannot mean that every one of the 800 to 1000 or so drugs are *in fact* transformed into an

amorphous state using the described method. Nor does it suggest that *each and every* such drug would be transformed in the amorphous state. If so, the term "and" would have been used instead of "or" in the language relied upon by the Examiner in column 12 of the '300 patent.

A fundamental problem with the reasoning set forth in the Office Action is that it is a strictly theoretical and academic exercise of attempting to manufacture a claimed composition of matter where there is no support for the same in the material cited. "Although lack of unity of invention should certainly be raised in clear cases, it should neither be raised nor maintained on the basis of a narrow, literal or academic approach." M.P.E.P. § 1850, II., ¶4. Here, the Examiner is attempting to use an academic approach founded on conjecture and speculation to imagine by hindsight the theoretical possibility of a composition of matter where there is no objective evidence that the method taught in the '300 patent necessarily would produce such a substance. Moreover, Applicant's case was filed several years after the '300 patent published, and Applicant's disclosure teaches, even after publication of the '300 patent, that "tamsulosin in the form of the hydrochloride salt *has not been known to exist in different crystal forms* . . . Thus the amorphous form of tamsulosin hydrochloride *has not been described to date*." WO 2005/075416, p. 2, ¶2. The M.P.E.P. unambiguously instructs that "the benefit of any doubt [is to be] given to the applicant." M.P.E.P. § 1850, II., ¶4.

Because the reasoning of the Office Action is premised on conjectural assumptions about what might be made from a process that lists hundred of candidate compounds that could potentially be converted to one of several different forms (or not at all) with no clear evidence to show that an amorphous form of tamsulosin hydrochloride was ever even specifically contemplated or necessarily would have been produced, and because the opinion of Applicant with regard to this substantive fact issue is directly (and explicitly in Applicant's application) at odds with the Examiner's speculation, this is precisely the type of situation taught in the rules where an Examiner should yield to and give the benefit of the doubt to the Applicant.

Furthermore, the alleged lack of inventive step is based on consideration of a combination of references said to teach or suggest the subject matter of the alleged common technical feature. While no convincing showing is made that a person of skill would clearly have been motivated to combine these references to arrive at Applicant's claims directed to tamsulosin hydrochloride in the amorphous form, the fact is that the Examiner's entire procedure in citing art in this manner at this time and in support of a restriction requirement represents an improper, unwarranted, and

non-statutory attempt to shift the burden of demonstrating patentability to the Applicant and a related improper and unwarranted attempt to pre-judge the merits of the claimed invention before reaching the stage of prosecution involving substantive examination of the claims. Applicant should not be forced to attempt to demonstrate patentability of his claims merely to avoid otherwise unfounded and improper attempts to force him to separate closely related claim groups into separate prosecutions. As such, this restriction requirement founded upon a unity requirement that requires premature adjudication of patentability is contrary to law and established USPTO procedure, and must be withdrawn.

In view of the foregoing, Applicant respectfully requests reconsideration of the Requirement for Restriction and removal of the same.

III. Restriction Is Not Reasonably Required Under 35 U.S.C. § 121 In This Case

In addition to points made above, Applicant further notes that the claims of the various Groups are plainly very closely related and it is evident that their respective classes would be thoroughly cross-referenced, and that many of the same classes (or subclasses) would be searched regardless of whether one or all the groups was examined in this application.

As the Examiner knows, restriction is not "required" by 35 U.S.C. §121. Congress wisely gave the Commissioner the "discretion" to require restriction. According to 35 U.S.C. § 121 "... the Commissioner ***may*** require the application to be restricted...." (emphasis added). Likewise, the MPEP § 803 lists two criteria that both must be present for restriction to be proper:

1) The inventions must be independent or distinct; and
2) There must be a ***serious*** burden on the Examiner if restriction is not required (emphasis added).

As noted above, these requirements are conjunctive. Since the Examiner has not shown any serious burden if examination of all the claims is conducted in one prosecution and the claims plainly are drawn to closely related subject matter, neither criteria are even arguably satisfied and Applicant respectfully asserts that the restriction cannot properly be maintained.

In the event this response is not timely filed, Applicant hereby petitions for the appropriate extension of time and requests that the fee for the extension along with any other fees which may be due with respect to this paper be charged to our **Deposit Account No. 12-2355.**

Respectfully submitted,

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